catheter assembly classified in class 604, subclass 43) is made with traverse for immediate prosecution.

Remarks

Restriction is authorized under 35 U.S.C. §121 and 37 C.F.R. §1.141(a) and is proper only if "two or more independent and distinct inventions are claimed in one application."[1] Restriction in accordance with statutory authority is permissible, but never required.[2]

Restriction is discretionary with the examiner; a requirement for restriction must be evaluated on a case-by-case basis. Two basic reasons for requiring division of claims for independent and distinct inventions presented in a single application are: (1) the governmental interest in obtaining proper[3] revenue from filing and issue fees for each application; and (2) the interest in maintaining the integrity of the classification system for examining applications. *Ex parte Yale*, 1869 C.T. 110 (Comm'r. Pat. 1869). The governmental interests must be balanced with and against the standards of statutory law, federal regulations, administrative policies, and the interests of the applicant, to reach a just and proper result.

The terms "independent" and "distinct" have separate and different meanings. M.P.E.P. §802.01. As used in 35 U.S.C. §121, an "independent" invention means an invention having no disclosed relationship between the two or more subjects claimed (i.e., the two or more subjects claimed are unconnected in design, operation or effect). Examples of subjects unconnected in

---

[1] The Commissioner interprets this requirement as authorizing restriction if the inventions are independent or distinct, notwithstanding the clear use of "and" in the statutory language. MPEP §803.

[2] "If two or more independent and distinct inventions are claimed in one application, the Commissioner **may** require the application to be restricted to one of the inventions..." 35 U.S.C §121.

[3] As discussed below, "proper revenue" does not mean as much revenue as possible by issuing improper division or restriction requirements; rather, "proper revenue" means just compensation for examining a patent application directed to each truly independent and distinct invention.

design, operation or effect include "a claimed process and apparatus incapable of being used to practice the process." MPEP §802.01. Accordingly, a process and an apparatus used in practicing the process (as exists in the present invention) are, by definition, not independent. M.P.E.P. §802.01. Inventions are "distinct" if the inventions are: (1) capable of separate manufacture, use, or sale as claimed; and (2) patentable over each other. M.P.E.P. §802.01.

Assuming two claimed inventions are independent or distinct in this sense, the Commissioner further requires the examiner to show that there would be some extra burden on the Patent and Trademark Office (PTO) to examine the separate inventions in one patent application.

> Every requirement to restrict has two aspects, (1) the reason (as distinguished from the mere statement of conclusion) why the inventions *as claimed* are either independent or distinct, and (2) the reasons for insisting upon restriction therebetween.

M.P.E.P. §808. This two-prong analysis was adopted by the Patent Office in 1975. See Notice of April 9, 1975, 934 O.G. 450.

The requirement of demonstrating extra burden on the PTO is satisfied if the examiner gives a reason approved by the Commissioner for exercising the authority provided by 35 USC §121 to require restriction. In accordance therewith, restriction can only be required if one or more of the following are characteristic of the restricted claim groups: (1) the claim groups are subject to *separate classifications;* (2) the inventions defined by the claim groups have acquired a *separate status in the art*, meaning that the classification system of the PTO may be changed in the future to classify the separate inventions in different classes and subclasses; or (3) a *separate field of search* would be required for the separate inventions, meaning a complete search would

require examination of other classes and subclasses that differ for each separate invention. §808.02.

Examiner's burden to show independent and distinct inventions has not been satisfied

In the present application, the examiner characterizes the inventions as distinct. For groups I and II, the examiner cites MPEP § 806.05 (f) as satisfied, stating that the product as claimed can be made by another and materially different process; the "multilumen catheter assembly can be made by an injection molding process."

Applicant disagrees, and contends that an injection molding process is not "another and materially different process" for making the multilumen catheter assembly. Certain method steps present in the process claims of the instant application can include injection molding techniques (e.g., see page 16, line 25 through page 17, line 7); therefore, injection molding would not be "another and materially different process" for making the product of the present invention. Further, certain other method steps included in the claims for making the multilumen catheter assembly include limitations precluding injection molding as a method of performing the respective step, thereby precluding injection molding as "another and materially different process" for performing the entire claim (i.e., making the multilumen catheter assembly). Accordingly, in either instance, above, injection molding would not be "another and materially different process" for making the product of the present invention. Therefore, the examiner has not met the burden of proving that the inventions of groups I and II are distinct under MPEP § 806.05 (f).

For groups II and III, the examiner cites MPEP § 806.05 (h) as satisfied, stating that the process of using the product as claimed can be practiced with another materially different product, such as using separate single lumen catheters.

Applicant again disagrees, and contends that the process of using the product *as claimed* can not be practiced using separate single lumen catheters. Certain limitations exist in the claims of group III (claims directed to the process of using the product) precluding separate single lumen catheters from satisfying the claim (e.g., see the unitary catheter limitation). Therefore, the examiner has not met the burden of proving that the inventions of groups II and III are distinct under MPEP § 806.05 (h), as use of separate, single lumen catheters to practice the process of using (inserting) the catheter assembly, as claimed, can not be accomplished. As stated in MPEP § 806.05 (h), if the alternative suggested by the examiner cannot be accomplished, the burden is on the examiner to support a viable alternative or withdraw the restriction requirement.

Examiner's requirement of demonstrating extra burden on the PTO has not been satisfied

As discussed, even if two or more claim groupings are independent or distinct as claimed (not the case in the present invention, however), there must also be a serious burden on the examiner to require restriction. M.P.E.P. §803. If the search and examination of the an entire application can be made without serious burden, the examiner must examine the application on its merits, in its entirety, even though the application includes claims to distinct and/or independent inventions. M.P.E.P. §803.

In examiner's paragraph 3, the examiner offers only one reason to demonstrate extra burden on the PTO. The examiner states that the inventions "have acquired a separate status in the art as shown by their different classification." This statement, however, substantiates a two-way restriction at most, in the instant case, and not the three-way restriction called for in the communication. Recall that group I (claims 1-19) are classified in class 264, subclass 255, while both groups II (claims 20-30) and III (claims 31-35) are classified in class 604, subclass 43.

Accordingly, the examiner's requirement of demonstrating extra burden on the PTO has also not been satisfied.

Practical and equitable considerations mandate review of applicant's claims as a single application

A close examination of the practical and equitable considerations surrounding the present case compels withdrawal of the examiner's restriction requirement and requires inclusion of all the claims presented by applicant in a single patent application. The salient consideration for insisting upon restriction and determining the propriety of a restriction requirement is the scope of the examiner's search for prior art. Applicant is entitled to a full and thorough search of the prior art as a consequence of having filed his application and having paid the statutory application fee. 35 U.S.C. §131.

The examiner's instructional guidelines for performing such a search for any application are set forth in the M.P.E.P. The guidelines compel the examiner to search in classes and subclasses in which independent and distinct (as defined by the M.P.E.P.) inventions would be classified. For example, §904.01(c) recites:

> "Not only must the art be searched with which the invention claimed is classifiable, but also all analogous arts regardless of where classified. The determination of when arts are analogous is at times difficult. It depends upon the necessary essential function or utility of the subject matter covered by the claims, and not upon what it is called. (emphasis added).

MPEP §904.01(d) recites:

> A proper field of search includes the subclass in which the claimed subject matter of an application would be properly classified.
>
> In outlining a field of search the examiner should note every class and subclass under the U.S. Patent Classification system and other organized systems of literature, that may have material pertinent to the subject matter as claimed. Every subclass, digest and cross reference art collection pertinent to each type of invention claimed should be listed,

> from the largest combination through the various subcombinations to the most elementary part. **The search should extend to all probable areas relevant** to the claimed subject matter and should cover the disclosed features which might reasonably be expected to be claimed.
>
> The examiner should plan a search that not only covers the claimed subject matter, but one that also covers the disclosed features that might reasonably be expected to be claimed.

MPEP §904.02 recites:

> It is a prerequisite to a speedy and just determination of the issues involved in the examination of an application that a careful and comprehensive search, commensurate with the limitations appearing in the most detailed claims in the case, be made in preparing the first action on the merits so that the second action on the merits can be made final or the application allowed with no further searching other than to update the original search. It is normally not enough that references be selected to meet only the terms of the claims alone, especially if only broad claims are presented; but the search should, insofar as possible, also cover all subject matter which the examiner reasonably anticipates might be incorporated into applicant's amendment.
>
> It thus results that the examiner finds references that, while not needed for treating the claims, would be useful for forestalling the possible presentation of claims to other subject matter regarded by applicant as his or her invention, and claimable with the subject matter being currently claimed, but shown to be old by these references.

From the above-quoted guidelines, it is clear that the scope of a proper search includes:

> (1) classes and subclasses in which the claimed subject matter is classified;
>
> (2) classes and subclasses that may have material pertinent to the claimed subject matter;
>
> (3) classes and subclasses containing subject matter present in the disclosure which might reasonably be expected to be claimed during the prosecution; and
>
> (4) classes and subclasses that may contain subject matter disclosing material related to features which might reasonably be expected to be claimed.

Therefore, only where inventions are independent and distinct (as defined by the M.P.E.P.), and require non-overlapping searches, is restriction proper. The various disclosed methods of making and inserting a multilumen catheter assembly, along with the assembly itself, are interrelated, are all directed to related technology, and all merit patent protection. Thus, the examiner will not be unduly burdened by searching and examining all of the claims presented by applicant in a single application. The examiner's search will not be narrowed or reduced by compliance with the restriction requirement, since applicant has clearly manifested his intent to claim each novel and non-obvious aspect of the invention as evidenced by the claims in the application.

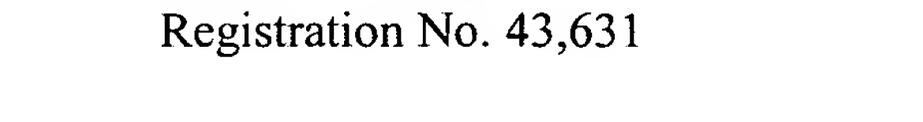
Cost to applicant of the proposed restriction would be unduly burdensome

While the PTO has a legitimate interest in obtaining proper revenue, it does not have unrestrained power to tax inventors. Applicant is entitled to obtain patent protection on each of the non-obvious inventive aspects of the multilumen catheter assembly and the methods of making and inserting same. If applicant is forced to divide this application into three separate patent applications, applicant will be unduly and unfairly burdened with fees and costs associated with prosecuting and maintaining three patents instead of one.

Conclusion

For the foregoing reasons, applicant respectfully requests reconsideration and withdraw of the restriction requirement. Notification that the restriction requirement has been reconsidered and withdrawn is respectfully solicited.

Respectfully submitted,



Bruce D. George
Registration No. 43,631

Woodcock Washburn LLP
One Liberty Place, 46th Floor
Philadelphia, PA 19103
ph: 215-557-5994
fax: 215-568-3439
e-mail: bgeorge@woodcock.com